How to play the role of HTA in evidence-based decision making in China?

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China’s Health System Context

- Universal population coverage through three main health insurance schemes
- Sound primary healthcare network with attention on preventive care
- Inequitable access to health care on account of great variety of socio-economic situation among regions and population groups
- High expenditure burden on the patients and their families
HTA-related Activities

- Company-sponsored HTA/PE researches for specific products or therapeutic categories
- Academic communication and discussions
- PE guidelines formulated and published
- Discussions on application of HTA evidences into decision making including essential medicines list update, reimbursable drug list update, government pricing management and clinical guidelines/pathway development

HTA and Decision-making
Challenges for HTA application

- Lack of mechanisms to introduce HTA into decision making
- Inconsistent understanding of stakeholders about HTA role in decision making
- Limited capacity to conduct HTA and utilize HTA evidences
  - Few influential HTA institutions
  - Shortage of professionals in HTA
- Shortage of basic data, especially on epidemiology and cost
Hong Kong and Malaysia – 
HTA Development and Challenges Ahead

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HTA development in Asia

- **Rapidly Changing**
  - South Korea
  - Taiwan
  - Thailand

- **Moderately Changing**
  - China
  - Japan
  - Singapore

- **Gradually Changing**
  - India, Pakistan
  - Malaysia, Philippines
  - Hong Kong
Hong Kong

- 2010 Population = ~ 7 million
- 2010 GDP = US 322 billion*
- 2010 GDP per capita = US 45,736*

### Major Health Indicators in 2005 and 2006

<table>
<thead>
<tr>
<th>Major Health Indicator</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crude birth rate (No. of registered live births per 1,000 population)</td>
<td>8.4</td>
<td>9.5</td>
</tr>
<tr>
<td>Crude death rate (No. of registered deaths per 1,000 population)</td>
<td>5.7</td>
<td>5.5</td>
</tr>
<tr>
<td>Age-standardised death rate (No. of deaths per 1,000 standard population)</td>
<td>3.8</td>
<td>3.5</td>
</tr>
<tr>
<td>Infant mortality rate (No. of deaths per 1,000 registered live births)</td>
<td>2.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Maternal mortality ratio (No. of deaths per 100,000 registered live births)</td>
<td>3.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>73.6</td>
<td>73.4</td>
</tr>
<tr>
<td>Female</td>
<td>84.6</td>
<td>85.5</td>
</tr>
</tbody>
</table>

Notes:
The Population By-census conducted in July to August 2006 provides a benchmark for revising the population figures compiled since the 2001 Population Census. In the above table, population-related figures for 2006 have been revised accordingly.


Source: Department of Health website, Hong Kong SAR, updated on 23 Oct 2007.

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### Challenges to the HK Health Care System

- Aging population
- Rising prevalence for some chronic diseases
- Equity in resource allocation
- Low awareness of concepts of primary health care
- Over-reliance on secondary care
- General inadequacy of health knowledge
- Imbalance between public and private sectors in service provisions
- Inflation in cost of new health technologies
- Sustainability of the system
Drug budget and approval in public sector

- Around 5-8% of the annual health care budget
- Only little regards given to long-term cost-effectiveness data, more concerned about immediate budget impact
- PE guidelines not yet developed
- HTA system not in place

Health Care System of HK (overall)

- HK is facing more or less the same problems encountered by other jurisdictions in other parts of the world
- HK is not exactly doing things that are very different from overseas practices
- Overall performance is not bad – small budget but good outcomes
- BUT
  - present situation is a result of severe restriction on the use of new health care technologies
  - standard of medical care?
  - international reputation?
Future Trends

The government will take forward a major Health Care Reform through 3 initiatives

• formulating a regulatory framework and operational details for the territory-wide insurance scheme **Health Protection Scheme (HPS)**
• reviewing the health care manpower strategy
• facilitating health care service development

Expected to put forward specific proposals in the first half of 2014

Latest Developments

• Government of HK’s recent plan to start incorporating HE data into new drug evaluations

• Questions:
  - Guidelines
  - Consultation with stakeholders
  - Timeline
  - Capacity building
# HTA in Malaysia

## Current Healthcare System

<table>
<thead>
<tr>
<th></th>
<th>Public</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td>148 hospitals, 808 clinics(^1)</td>
<td>209 hospitals, 6,371 clinics(^2)</td>
</tr>
<tr>
<td><strong>Cost to patients</strong></td>
<td>Low (Heavily subsidized care)</td>
<td>High (Fee for service)</td>
</tr>
<tr>
<td><strong>Clientele</strong></td>
<td>All (mostly lower income)</td>
<td>Middle to high income</td>
</tr>
<tr>
<td><strong>Utilisation</strong></td>
<td>Overcrowded</td>
<td>Faster services</td>
</tr>
<tr>
<td><strong>Medical personnel salaries</strong></td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td><strong>Doctor-patient ratio(^3)</strong></td>
<td>1:1384</td>
<td>1:486</td>
</tr>
</tbody>
</table>

Health Care Financing in Malaysia

- Public services heavily subsidized by government (~ 95-97%), mostly through general taxation
- Private health services: by out-of-pocket fees (73.2%) or private health insurance schemes (13.7%)
- Current spending on healthcare: 4.75% of GDP but under pressure to increase to 7% by 2020
- All these have led to:
  - huge budget for health services but efficiency unknown
  - perpetual drain of health care providers to private sector
  - over-crowding and long waiting times at public hospitals
  - little new/innovative health technologies adopted for use
  - sustainability unknown

Current Issues

1. Change of disease patterns
2. Change of demographic patterns
3. Imbalance in healthcare utilisation
4. Challenges in quality of care
Proposed Healthcare Reform

- Integration of public & private healthcare sectors
- Improve health equity and healthcare quality
- Evidence-based decision making
- A health care financing scheme that is at par with developed countries
- National Health Financing Scheme – financial risk protection to avoid catastrophic healthcare expenditure
- Higher transparency to enhance accountability to tax payers

Malaysia Pharmacoeconomic Guidelines 2012

Purpose:
To provide guidance for conducting pharmacoeconomic analysis in Malaysian context

- Developed by the MOH Pharmaceutical Services Division
- Recommending CEA, CUA & Budget Impact Analysis
- Intended to be used in conjunction with modified requirements (under development) for MOH formulary listing
Summary

- Malaysia is on the eve of a major health care reform
- HE data will be utilized as an evidence-based approach in achieving greater transparency and accountability
- Capacity to be built up urgently

Acknowledgement

- Prof Vivian Lee of CUHK
- Dr Soraya, Mr Adrian Goh and Mr Wilson Low of Veras Research Malaysia
HTA in Thailand

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Outlines

- Country background
- HTA overview
- Updates
- Challenges
Population: 69.52 million people

GDP per capita: US$4,971 (2011)

Health insurance scheme
- Universal Coverage (UC)
- Civil Servant Medical Benefit Scheme (CSMBS)
- Social Security Scheme (SSS)

UC 75%, CSMBS and SSS 22%.

% of annual income spent for health care services: 4%

Life expectancy at birth: 74 years
HTA overview

- HTA agency e.g. HITAP
- National HTA guideline
- National Essential List of Medicines (NLEM)
  - Listing e.g. atorvastatin was not listed in NLEM 2008
  - Negotiating and setting price list e.g. 40% price reduced
    - Decision making tools
      - ICER, Budget impact analysis (BIA)

Teerawattananon et al. 2009
**HTA process: compared with EU**

- Initiation
- Prioritization
- Commissioning
- Policy question
- Discussion, conclusion, recommendation
- Defining research question
- Background collection
- HTA protocol
- External review
- Final report
- Dissemination
- Use of HTA
- Update of the HTA

Garrido et al. 2008

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**Updates: 2012**

- **HTA process guideline: Good governance**
  - Transparency, participation, responsibility, quality, timeliness, consistency, appeal

- Revision of HTA national guideline in 2012

- Examining WTP per QALY
Challenges

- Assessment VS Appraisal
- One threshold fits all: £1,000 per QALY
- Capacity e.g. human & data
- Policy makers
- BIA
- HTA agency
- Public awareness

Ex: Rheumatoid arthritis

<table>
<thead>
<tr>
<th>Comparator</th>
<th>ICER (Baht/QALY)</th>
<th>% Threshold of ICER</th>
<th>Current unit price</th>
<th>Negotiation unit price</th>
<th>% Discount of current unit price</th>
</tr>
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<tbody>
<tr>
<td>Rituximab</td>
<td>1,153,909</td>
<td>10.39%</td>
<td>62,814 Baht/500 mg</td>
<td>8,065 Baht/500 mg</td>
<td>87%</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>1,687,240</td>
<td>7.11%</td>
<td>33,598 Baht/400mg</td>
<td>4,600 Baht/400mg</td>
<td>86%</td>
</tr>
</tbody>
</table>

Ex: Rheumatoid arthritis

Comparator: Rituximab, Tocilizumab
ICER: 1,153,909, 1,687,240
% Threshold of ICER: 10.39%, 7.11%
Current unit price: 62,814 Baht/500 mg, 33,598 Baht/400mg
Negotiation unit price: 8,065 Baht/500 mg, 4,600 Baht/400mg
% Discount of current unit price: 87%, 86%
Transferability
- Coxibs
  - celecoxib and etoricoxib are not cost effective in UK...therefore it implies they are not cost effective in Thailand....
- PPI
  - a study reported ICER US$763 per QALM, so it was 274,680 Baht per QALY...therefore it is higher than Thailand cost-effective threshold....

Cost-effectiveness of human papillomavirus vaccination and cervical cancer screening in Thailand

Economic Evaluation of Policy Options for Prevention and Control of Cervical Cancer in Thailand
Conclusions

- Both government and pharmaceutical companies put efforts on capacity building.

- Dynamic system
Health Technology Assessment in a Resource Constrained Setting: Real Challenges Facing Asia

ISPOR Asia Consortium Forum
During the ISPOR 15th Europe Congress
November, 2012

by
Bong-Min Yang, PhD
Surachat Ngorsuraches, PhD, RPh
Wen Chen, PhD
Kenneth KC Lee, MPhi, PhD

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Overview of Asia HTA and Korean HTA

for Asia HTA Forum-ISPOR Europe 2012

by

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Professor, Seoul National University, South Korea

Overview

• Policy makers and stakeholders in health financing are deeply concerned about the difficulties involved (recently more so in Korea, Japan, China, Taiwan, Thailand, ….)

• Health authorities began looking into the pharma sector. Starting with Korea, the concept of HTA has been introduced in the Asia region

• Two versions of drug policy is an emerging trend; one for the new drug and the other for the generics (including off-patent-originals)
HTA Positioning in Asia

- At the regulatory stage: with a regulatory body
  - Korea(HIRA), Taiwan(CDE), Thailand(HITAP under MoH)
  - Korea in next phase with HTA frame to be refined, but no major changes
- Intermediate stage: PEG in place or voluntarily submitted data reviewed
  - China, Japan, Singapore, Malaysia,
- Developing Stage: looking into HTA possibility
  - India, Philippines, Pakistan


Korean Case
Drug R&P Structure

• Under the environment of
  – NHI financial pressure by the speedy aging society
  – Growing share of drug expenditure
  – Concerns raised on NHI insolvency

• Drug policies in place: 3 schemes
  – (i) HTA – value for money for new drugs
  – (ii) Volume-price Agreement (for controlling drug spending) – all drugs in the formulary
  – (iii) Price cut – price adjustment of off-patent generics

New Drug HTA
Procedure for Reimbursement Decision

- Production or import of a new drug
- K-FDA approval of marketing
- HIRA: Decision on listing
- NHIC: Negotiation on drug pricing
- Inclusion of the drug in the formulary

How much is PE data (CEA) weighed in actual reimbursement decisions?

- PE data is one of many factors involved in value decisions
- However, it may well function as an entry point
- Which seems the case in many other countries of early HTA adopters
- This is why the pharma industry is so sensitive to PE regulation
Listing New Drugs with the HTA System

- Decisions to reimburse new drugs decreased while decisions not to reimburse increased
  - Between Jan 2007 and June 2010, a total of 248 drugs applied for reimbursement in the NHI
  - About 27% (66/248) were denied reimbursement, previously none denied
  - About 61% (40/66) of those denied drugs were due to lack of evidence or unacceptable cost-effectiveness (source: HIRA & Kim(2010))

Recent Refinements of PE Submission Guideline

- Methodology
  - Use CUA when using QALY is proper
  - Use CEA when estimating QALY poses difficulty
  - Indirect comparisons acceptable
- QALY
  - Generic utility index preferred
  - Results from using patient specific index can be added
- Cost estimates
  - Social perspective confirmed
  - But costs may not be too broad (i.e., issue of productivity loss)
- Experts opinion
  - Must specify who are consulted, how they are chosen, why they are selected